UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,404	02/13/2004	Roger K. Sunahara	UM-08794	7762

7590 11/21/2006

Tanya A. Arenson
MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,404	SUNAHARA ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,11-15 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9, 11-15 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/04 & 10/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Applicant's response on July 12, 2006 to the Office Action mailed on March 3, 2006 is acknowledged. Claims 1 and 3-15 are pending in the current application. Claim 10 is canceled. New claims 21-23 have been added. Claims 1, 3-9, 11-15 and 21-23 are present for examination.

Information Disclosure Statement

The information disclosure statement filed on December 06, 2004 and October 07, 2005 for which a copy of the patent publication has been submitted in this application has been reviewed in full.

Oath/Declaration

The oath or declaration submitted on July 19, 2004 has been reviewed and is in compliance with 37 CFR 1.56.

Withdrawn - Claim Rejections - 35 USC § 101

Claim 10 was rejected under 35 U.S.C. 101 because the claimed invention lacked patentable utility. This rejection has been withdrawn following cancellation of the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The utility of the method claimed lies in the utility of the product produced. Niether the

prior art nor the specification teach a specific or substantial utility for a ligand of the orphan receptor. It appears that the main utility of the product of the method is to carry out further research to identify the function of an orphan receptor and possible diseases associated with said function. Substantial utility defines a real world use. *See In* re Brenner, United States Supreme Court, 1996, 383 U. S. 519, 148 USPQ 689. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Withdrawn - Claim Rejections - 35 USC § 102

Claims 1, 5, 6 and 14 were rejected under 35 U.S.C. 102(a) as being anticipated by Gille et al. (Gille et a1. 2'(3')-O-(N-Methylanthraniloyl)-substituted GTP Analogs: A Novel Class of Potent Competitive Adenylyl Cyclase Inhibitors. Journal of Biological Chemistry Vol. 278, No15, pp12672-12679) which first appeared on line on February 3rd, 2003).

Applicant's argument has been carefully considered and was considered persuasive. Although Gille et al suggest that MANT-nucleotides could be used as fluorescent ligands for adenylate cyclase for the analysis of adenylate cyclase kinetics with high temporal resolution, the particular fluorescent MANT substituted nucleotides used in their experiment was useful as a competitive adenylyl cyclase inhibitors rather than a substrate for a nucleotide cyclase. Therefore the rejection of claims 1, 5, 6 and 14 has been withdrawn.

Withdrawn - Claim Rejections - 35 USC § 103

Claims 1, 3-9, 11-15 and now including claims 21-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Herr et al (US 2002/0064849 A1) in view of Gilles et al ("MANT-substituted guanine nucleotides: A novel class of potent adenylyl cyclase inhibitors", Life

Sciences 74, 271-279 (2003) (Gilles[1]). Applicant's argument has been carefully considered and has been found persuasive for the following reason. Although Gill et al suggest the use of other nucleotides with fluorophores such as BODIPY-substituted nucleotides to study the kinetics of adenylate cyclase (AC) in the context of identifying AC inhibitors they do not teach the use of said nucleotides with fluorophores in the method of assying nucleotide cyclas activity based on increase oe decrease of fluorescence. Therefore this rejection has been withdrawn.

Claims 1-7, 11-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Herr et al (US 2002/0064849 A1) in view of Rossomando et al. This rejection is maintained for the following reasons:

Applicants argue:

"The teachings of Herr have been previously described. Rossomando teaches that a fluorescent ATP analog, FoTP, can be utilized as a substrate by adenylate cyclase.
Rossomando further teaches that the fluorescent cyclized product (cFoMP) is purified from the other reaction products via HPLC prior to detection by fluorometry (page 2279, Experimental Procedures). Therefore, Rossomando only teaches fluorometric assay of purified cyclic FoMP... Rossomando only teaches the detection of a purified nucleotide cyclase and does not teach the detection of fluorescently labeled substrates to test for compounds that could modulate nucleotide cyclase activity..."

However as stated previously, Herr et al. teach a method of measuring adenylyl cyclase activity in a sample containing a human soluble adenylyl cyclase and a compound that can potentially affect the activity of said adenylyl cyclase by measuring the amount of cAMP formed from ATP. Herr et al measure the level of cAMP produced using a radioimmunoassay method. In addition as stated in pages 8-9 of the previous Office Action, the teaching by Rossomando et al clearly states that the use of fluorescent nucleotide analogues in adenylate cyclase reactions

is preferable in order to avoid problems of radioactive waste disposal [see page 2281, second column 2nd paragraph].

Therefore a person of ordinary skill in the art would be motivated to adapt the method of Herr et al who measure the level of cAMP produced using a radioimmunoassay with a method that uses a fluorescent BODIPY-FL-GTPγS as taught by McEwen and the teaching of Rossomando et al who clearly suggest the use of fluorescent nucleotide analogues in adenylate cyclase reactions. One of ordinary skill in the art would have a reasonable expectation of success because McEwen et al's teaching that various nucleotide analogues such as BODIPY-FL-GTPγS are suitable for fluorescent assays and disclose that binding of said fluorescent molecules increases upon binding to the alpha sub-unit of G proteins.

Withdraw - Claim Rejections - 35 USC § 103

Claims 1, 3-9, 12-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rammers et al (Fluorescent Guanine nucleotide analogues and G protein Activation, (Journal of Biological Chemistry, Vol. 269, No. 19, pages 13771-13778, 1994) in view of Holtwick et al. Smooth muscle-selective deletion of guanylyl cyclase-A prevents the acute but not chronic effects of ANP on blood pressure. PNAS 2002. Vol. 99, No. 10, pp 7142-7147. This rejection is withdrawn because the references above are conserned with the use of fluorescent Guanine nucleotide Analogs in G protein activation wherein the nucleotide analogue is hydrolized and fluorescence measured in the presence or absence of masopran. The instant claims are drawn to enzymes involved at subsequent step in G protein signaling; namely a nucleotide cyclase enzyme in the presence of a fluorescently labled nucleotide. Thus this rejection has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew Gebreyesus PhD.

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER